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Withholding Info from FDA Could Trigger Punitives: Judge

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A drug manufacturer may be held liable for punitive damages on a theory of "implied malice," a federal judge has ruled, where evidence suggests the manufacturer withheld information from the U.S. Food & Drug Administration that would have led to stronger warning labels.

In his 25-page opinion in *Wolfe v. McNeil-PPC Inc.* , Senior U.S. District Judge Jan E. DuBois said a jury must decide whether the manufacturer of Children's Motrin withheld from the FDA reports of two instances in which patients developed Stevens-Johnson Syndrome, a rare and life-threatening condition affecting the skin in which cell death causes the epidermis to separate from the dermis.

Lawyers for plaintiff Kiley Wolfe argued the evidence showed that McNeil concealed from the FDA two cases of SJS found in patients during a massive study it commissioned on the safety of selling Children's Motrin over the counter.

Although McNeil acknowledged receiving reports of the two cases, the plaintiffs argued that a subsequent Clinical Study Report issued by McNeil describing the results of the study did not mention the two reports.

Lawyers for McNeil insisted that the FDA was apprised of the two reports.

But DuBois concluded the plaintiffs evidence was enough to raise a dispute that must go to the jury.

Although DuBois said it "may be true" that the FDA was given the reports, he found that "a reasonable jury viewing the evidence in the light most favorable to plaintiff could conclude otherwise."

DuBois also found that if the jury concludes that McNeil "deliberately concealed information from the FDA — both to win FDA approval of OTC Children's Motrin and to avoid the need to warn of SJS or its symptoms — the jury could well find that plaintiff demonstrated, by clear and convincing evidence, the sort of outrageous conduct that would justify the imposition of punitive damages."

According to court papers, Kiley Wolfe was 9 years old in 1996 when she developed a headache, stomach pains and a fever, and her pediatrician recommended Children's Motrin.

When her symptoms did not subside and Wolfe developed a rash on her cheeks, nurses at the pediatrician's office advised her mother to continue giving the Motrin.

Several days later, when Wolfe's rash worsened, she was taken to Boston Children's Hospital where doctors diagnosed her with Stevens-Johnson Syndrome.

During her hospitalization, her symptoms worsened to include an acute case of vanishing bile duct syndrome. Because of damage to her liver, Wolfe eventually required a liver transplant.

The suit alleges that McNeil was aware of the need for stronger warning labels due to the possibility of SJS in a small number of patients, but resisted changing the labels until 2006 when the FDA recommended it.

The prior label told patients to "call your doctor" if a rash occurs. The new label tells patients to "seek medical help right away" if they see skin reddening, rashes or blisters.

Wolfe's mother, Janet Leland, testified that she hadn't read the warning labels before giving her daughter the first dose, but that she had consulted the package several times when her daughter's condition was getting worse.

The suit, filed by attorneys Thomas N. Sweeney and Joseph L. Messa of Messa & Associates in Philadelphia, along with Darryl J. Tschirn of La Jolla, Calif., and John M. Robin of Covington, La., alleged negligence, warranty and strict liability claims, as well as failure-to-warn and consumer protection claims.

Now DuBois has concluded that only the failure-to-warn claims and a claim for punitive damages may proceed.

McNeil's lawyers — Kenneth A. Murphy and Kadene K. Chin of Drinker Biddle & Reath — argued that the failure-to-warn claims should be dismissed because they are pre-empted by federal law and because Wolfe cannot show causation.

DuBois disagreed, saying the U.S. Supreme Court's 2009 decision in *Wyeth v. Levine* held that "FDA approval of a drug label does not bar recovery in a state-law failure-to-warn action."

The defense team insisted that, even under *Levine* , the claim should fail because the FDA declined a citizen petition's request to require manufacturers to include a specific reference to SJS on ibuprofen warning labels.

But DuBois said the FDA had also "agreed with the citizen petition that labeling for drugs like Children's Motrin 'should be improved to warn consumers about the risks of severe skin reactions associated with [over-the-counter] ibuprofen products.'"

Although the FDA didn't see the need to mention SJS by name, DuBois said, it agreed that a description of seriously troubling symptoms should be added.

As a result, DuBois concluded that the *Levine* exception should not apply because McNeil "failed to adduce 'clear evidence' that the FDA would have rejected the stronger labeling plaintiff believes was required."

Turning to the issue of punitive damages, DuBois said he had previously ruled that Maine law applied to that claim, so that punitive damages may be awarded "only upon a showing that the defendant acted with express or implied malice."

McNeil argued that even if Wolfe can show that reports of SJS were withheld from the FDA, the claim would be barred by the U.S. Supreme Court's 2001 decision in *Buckman v. Plaintiffs' Legal Committee,* which held that a state-law claim for fraud on the FDA was pre-empted by federal law.

DuBois disagreed, saying "Maine's provision for the award of punitive damages in appropriate cases is not an 'attempt to police fraud against the FDA,'" but instead is "part of the state's traditional role of regulating matters of health and safety."

The evidence that McNeil concealed information from the FDA, DuBois said, "is not being used to establish liability in this case but to demonstrate that the offending failure-to-warn conduct was not merely sufficient to establish strict liability or negligence but was truly outrageous."

Murphy declined to comment on the ruling.

Messa, in an interview, said he was pleased with the judge's ruling on the failure-to-warn and punitive damages issues, but that the plaintiffs team is weighing whether to ask the judge to reconsider his dismissal of the consumer protection claim.

(Copies of the 25-page opinion in Wolfe v. McNeil-PPC Inc., PICS No. 11-0596, are available from The Legal Intelligencer. Please call the Pennsylvania Instant Case Service at 800-276-PICS to order or for information. Some cases are not available until 1 p.m.) •